Attachment to Ltr 12

PATENT
Docket No. 304142000201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Malaya CHATTERJEE et al.

Serial No.: 09/293,533

Filing Date: April 15, 1999

For: MONOCLONAL ANTIBODY 1A7 AND USE FOR THE TREATMENT OF MELANOMA AND SMALL CELL CARCINOMA

Examiner: L. Helms

Group Art Unit: 1642

DECLARATION OF KENNETH A. FOON, M.D.
PURSUANT TO 37 C.F.R § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Kenneth A. Foon, declare as follows:

1. I am an inventor on the above-referenced patent application.

2. I am a Professor in the Department of Internal Medicine, Associate Chief of the Division of Hematology and Oncology, and Director of the Barrett Cancer Center at the University of Cincinnati College of Medicine. A curriculum vitae is attached hereto as Exhibit A.

3. I am the director and medical supervisor of clinical trials using anti-idiotype antibody 1A7 to treat patients with melanoma in accordance with the teachings of the above-

referenced patent application. The details of these trials and data obtained therefrom are summarized in the following paragraphs.

4. In a trial, the details of which are described in Foon et al. (*J. Clin. Oncolgy* (2000), 18:376-384), 47 patients with advanced melanoma (American Joint Committee on Cancer stage IV melanoma with measurable metastatic disease) were administered various doses of TriGem® (TriGem is the registered trademark for monoclonal antibody 1A7) mixed with QS-21 adjuvant, weekly for 4 weeks and then monthly until disease progression. Forty three percent of patients had undergone prior therapy for metastatic disease, 55% had disease confined to soft tissue, and 45% had visceral metastasis.

5. In the trial described in paragraph 4, hyperimmune sera from 40 of 47 patients showed an anti-anti-idiotype (Ab3) response. The Kaplan-Meier-derived overall median survival duration for the 47 patients was not reached but was at least 16 months, which is superior to those reported from other phase II trials in which the expected survival durations are typically in the range of 5 to 10 months Most notably, one patient had a complete response, and 12 patients were stable from 14 to 37+ months as of the time of publication of the above-referenced article. The patient who achieved a complete response had multiple soft tissue sites of metastases and had remained in complete remission for 24 months as of the time of publication of the above-referenced article. These results are especially significant given the advanced disease state of the patients. The data from the trial suggest a clinical benefit in using 1A7 to treat patients with advanced melanoma.

6. In a second trial, which is described in Safa et al. (abstract published in Proceedings of American Society of Clinical Oncology (ASCO) (2001), Vol. 20, abstract 1008, attached hereto as Exhibit B; and manuscript submitted for publication, attached hereto as Exhibit C), patients in the adjuvant setting who had curative resection of the primary lesion and lymph node metastases (American Joint Committee on Cancer stage III melanoma) were studied. Patients who had a positive sentinel lymph node biopsy for melanoma had a complete lymphadenectomy. Sixty nine patients were administered antibody 1A7 (25 patients also

received high dose interferon Alfa-2b (HDI)). Patients were administered 1A7 for 4 weeks, and then monthly until disease recurrence.

7. In the trial described in paragraph 6, all patients generated active immune responses with high titer anti-GD2 IgG responses and many had measurable CD4 T cell responses. The overall survival (OS) and relapse-free survival (RFS) at a median follow-up of 2 years for patients treated with 1A7 alone (without HDI) was 72% (7 deaths in 44 patients) and 50%, respectively. These data are comparable to those obtained when patients are treated with HDI, which are 78% (OS) and 62% (RFS), as reported in a personal communication from Dr. John Kirkwood of the Division of Hematology-Oncology and Department of Pathology, Department of Medicine, University of Pittsburgh Cancer Institute Melanoma Center, University of Pittsburgh Medical Center, Pittsburgh, PA. Dr. Kirkwood obtained this data from a two-year analysis of a trial comparing HDI with a GMK ganglioside vaccine in patients with high risk resected stage IIb and III melanoma. HDI has previously been reported to be beneficial for treating melanoma patients (see, for example, Kirkwood et al., *J. Clin. Oncol.* (1996), 14:7-17; Kirkwood et al., *J. Clin. Oncol.* (2000), 18:2444-2458; and Kirkwood et al., *Annals of Oncology* (2000), Supp. 4 to Vol. 11). Thus, the data from the trial described in paragraph 6 suggest a clinical benefit in using 1A7 for treatment of melanoma.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to by true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

5/29/01 Kenneth A. Foon

Date Kenneth A. Foon, M.D.

KENNETH A. FOON, M.D.
PROFESSOR, DEPARTMENT OF INTERNAL MEDICINE
ASSOCIATE CHIEF, DIVISION OF HEMATOLOGY AND ONCOLOGY
AND DIRECTOR, THE BARRETT CANCER CENTER
UNIVERSITY OF CINCIINNATI COLLEGE OF MEDICINE

I. PERSONAL DATA

Home Address:	1113 Belvedere St. Cincinnati, OH 45202
Home Telephone:	(513) 651-3598
Office Address:	The Barrett Cancer Center University of Cincinnati 234 Goodman St., Suite 1091 Cincinnati, OH 45267-0502
Office Telephone:	(513) 584-7698
Office Fax:	(513) 584-5680
E-Mail Address:	kenneth.foon@uc.edu

Social Security #:	372-48-6164
NCI Investigator #:	10881
Birth Date:	March 7, 1947
Certification:	1973, Diplomate, National Board of Medical Examiners 1978, Diplomate, American Board of Internal Medicine 1980, Diplomate, Subspecialty of Hematology, American Board of Internal Medicine 1981, Diplomate, Subspecialty of Medical Oncology, American Board of Internal Medicine
OH License No.	76212
Marital Status:	Married
Spouse Name:	Rebecca A. Garrett, M.D.
Children:	Melissa G. Foon (2/5/79) Michele G. Foon (10/2/80) Jeremy G. Foon (6/12/85

II. EDUCATION

1964 - 1966 University of Michigan
1966 - 1968 B.S., Wayne State University
1968 - 1972 M.D., Wayne State University

III. PROFESSIONAL EXPERIENCE

1977 - 1980 Hematology-Oncology Fellowship, University of California, Los Angeles, School of Medicine, Los Angeles, CA

1976 - 1977 Junior Assistant Resident, Washington VA and Georgetown University Hospitals, District of Columbia

1975 - 1976 Clinical Associate, Laboratory of Microbiology and Immunology, National Institute of Dental Research, National Institutes of Health, Bethesda, MD

1973 - 1975 Research Associate, National Eye Institute; Guest Worker, Laboratory of Microbiology and Immunology, National Institute of Dental Research, National Institutes of Health, Bethesda, MD

1972 - 1973 Straight Medicine Internship, University of California, School of Medicine, San Diego, CA

IV. ACADEMIC APPOINTMENTS

1999 – present Professor, Department of Internal Medicine, University of Cincinnati, Cincinnati, OH

1993 - 1999 Professor, Department of Internal Medicine, University of Kentucky, Lexington, KY

1991-1992 Adjunct Member, Department of Molecular and Experimental Medicine, The Scripps Research Institute

1987-1991 Professor, Department of Medicine, State University of New York at Buffalo, NY

1985-1987 Associate Professor, Department of Medicine, University of Michigan, Ann Arbor, MI

1984-1985	Associate Professional Lecturer in Medicine, George Washington
1981-1985	Senior Investigator, National Cancer Institute, Frederick, MD
1980-1981	Assistant Professor, Department of Medicine, University of California, Los Angeles, School of Medicine, Los Angeles, CA

V. HOSPITAL OR CLINICAL APPOINTMENTS

1999 – present	Director, The Barrett Cancer Center and Associate Director, Division of Hematology-Oncology, Department of Internal Medicine, University of Cincinnati, Cincinnati, OH
1993 – 1999	Director, Lucille Parker Markey Cancer Center and Chief, Division of Hematology and Oncology, Department of Internal Medicine, University of Kentucky, Lexington, KY
1991 – 1992	Associate Director for Clinical Research, Ida M. and Cecil H. Green Cancer Center, Scripps Clinic and Research Foundation; Adjunct Member, Department of Molecular and Experimental Medicine, The Scripps Research Institute, La Jolla, CA
1987 – 1991	Chief, Division of Clinical Immunology, Roswell Park Cancer Institute, and Professor, Department of Medicine, State University of New York at Buffalo, NY
1985 – 1987	Associate Chief and Director of Clinical Hematology, Division of Hematology and Oncology, and Associate Professor, Department of Medicine, University of Michigan, Ann Arbor, MI
1982 – 1985	Head, Clinical Investigations Section, Biological Therapeutics Branch, Biological Response Modifiers Program, Division of Cancer Treatment, National Cancer Institute-Frederick Cancer Research Facility, Frederick, MD
1984 – 1985	Associate Professorial Lecturer in Medicine, George Washington University, School of Medicine and Health Sciences, District of Columbia
1981 – 1982	Head, Monoclonal Antibody-Hybridoma Section, Biological Therapeutics Branch, Biological Response Modifiers Program, Division of Cancer Treatment, National Cancer Institute, Frederick, MD

1980 – 1981	Assistant Professor of Medicine, University of California, Los Angeles School of Medicine, Los Angeles, CA.

VI. CONSULTING

1985 – 1988	Board of Advisors, NeoRx Corporation, Seattle, WA
May 1, 1985	P01, Member, Memorial Sloan Kettering Cancer Center, NCI Site Visit Committee, New York, NY
October 1, 1985	P01, Member, NCI Special Review Committee
October 1, 1985	P01, Member, Stanford Medical Center, NCI Site Visit Committee, Stanford, CA
1985 – 1989	National Research Service Award Advisory Committee, National Institute of Health
March 1, 1988	P01, University of California at Davis, Sacramento, CA, Member, NCI Site Visit Committee
December 5, 1990	P01, Member, Immunomedics, Site Visit Committee, Morris Plains, NJ
November 11, 1991	P01, Stanford Medical Center, Member, NCI Site Visit Committee, Stanford, CA
February 10, 1992	P30, Member, University of Nebraska Cancer Center, NCI Site Visit Committee, Omaha, NE
July 13, 1993	P50, Member, NCI Special Study Section for AIDS Center Grants
1994 – 1995	Board of Advisors, Inex Pharmaceuticals Corp., Vancouver, B.C.
1994 - 1996	Health and Environment Laboratories, Eastman Kodak Company, Rochester, NY
April 13, 1994	P01, University of California at Davis, Sacramento, CA, NCI Site Visit Committee Chairman
June 19, 1994	2P01CA59326-03, Gene Therapy for Cancer, University of California at Los Angeles, Member, NCI Site Visit Committee
1995 -present	Scientific Review Panel, Israel Cancer Research Fund, New York, NY

February 14, 1995	2P01CA4499108, Therapy of Lymphoma/Leukemia with Monoclonal Antibodies, Fred Hutchinson Cancer Research Center, Member, NCI Site Visit Committee
June 12, 1995	1P30CA6953301, Oregon Cancer Center, Member, NCI Site Visit Committee
August 3, 1995	1P30CA6953301, Oregon Cancer Center, Member, NCI Site Visit Committee
February 6, 1996	NSABP Scientific Advisory Board, Operations Center Site Visit, Pittsburgh, PA
July 7, 1996	2P01CA5935005, Memorial-Sloan Kettering Cancer Center, Gene Therapy Program, NCI Site Visit Committee Chairman
October 7, 1996	1P30CA6953301A1, Oregon Cancer Center, Member, NCI Site Visit Committee
1996 - present	Director, Scientific Advisory Board, Titan Pharmaceuticals, Inc., South San Francisco, CA.
1997 - present	NCI Scientific Review Group-Subcommittee H
1999 – present	NCI Clinical Oncology Study Section
September 21, 1999	ACOSOG Site Visit, Chicago, IL
January 15, 2000	SuperGen Advisory Board Meeting, Phoenix, AZ.
January 13-16, 2000	SuperGen Advisory Baord Meeting, Phoenix, AZ.
February 15, 2000	NCI GI Intergroup State-of-Science Symposium
March 20, 2000	NCI Clinical Oncology Study Section, Bethesda, MD
May 7-8, 2000	IDEC Pharmaceuticals Meeting, San Diego, CA
May 16, 2000	American College of Surgeons/Titan Pharmaceuticals Meeting, Chicago, IL
June 7-9, 2000	NCI NIH Scientific Review Group – Subcommittee H Site Review, Rochester, MN
June 13-17, 2000	SuperGen, Rubitecan Advisory Board Meeting, Maui, HI

June 24, 2000	American College of Surgeons Semiannual Meeting, Chicago, IL
July 7-14, 2000	NCI Clinical Oncology Study Section, Bethesda, MD
Dec. 8-9, 2000	Abbott Pharmaceutical Advisory Panel, Chicago, IL
Jan. 14-15, 2001	Fulcrum Renal Cell Advisory Board Mtg. New York
Jan. 18-19, 2001	NCI Breast Intergroup Retreat, Washington, DC.
Mar. 15, 2001	NCI Scientific Review Group – Subcommittee H Teleconference

VII. TEACHING ACTIVITIES

Biotherapy: New Opportunities for Cancer Treatment, Grand Rounds, Scripps Clinic and Research Foundation, La Jolla, CA, February 28, 1992

Acute Leukemia, Internal Medicine Residency Program, University of Kentucky Medical Center, Lexington, KY, August 16, 1993.

Hodgkin's Disease, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, September 10, 1993.

Biologic Therapy and Growth Factors, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, October 8, 1993.

Anti-Idiotype Immunotherapy in Cancer Patients, Lecture-Division of Clinical Chemistry, University of Kentucky Hospital, Lexington, KY, April 27, 1994.

Chronic Lymphocytic Leukemia, Internal Medicine Grand Rounds, University of Kentucky Medical Center, Lexington, KY, July 6, 1994.

Acute Leukemia, Internal Medicine Residency Program, University of Kentucky Medical Center, Lexington, KY, August 16, 1994

Anti-Idiotype Vaccine Therapy of CEA positive tumors, Internal Medicine Research Seminar, University of Kentucky Medical Center, Lexington, KY, September 8, 1994.

Melanoma, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, February 3, 1995.

Lymphoma, Internal Medicine Residency Program, University of Kentucky Medical Center, Lexington, KY, March 23, 1995.

Chronic Lymphocytic Leukemia, Internal Medicine Residency Program, University of Kentucky Medical Center, Lexington, KY, April 28, 1995.

Overview of the Cancer Center, Health Administration, University of Kentucky Medical Center, June 22, 1995.

Non-Hodgkin's Lymphoma, Internal Medicine Residency Program, University of Kentucky Medical Center, Lexington, KY, September 11, 1995.

Hodgkin's Disease, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, September 15, 1995.

Non-Hodgkin's Lymphoma, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, September 29, 1995.

Acute Leukemias, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, February 2, 1996.

Leukemia and Lymphoma, Physician Assistants Lecture, University of Kentucky Medical Center, March 7, 1996.

Problem Based Learning Tutor Session, Internal Medicine, University of Kentucky Medical Center, April 1-15, 1996.

Low Grade Lymphomas, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, June 28, 1996.

Acute Leukemia, Internal Medicine Residency Program, University of Kentucky Medical Center, Lexington, KY, August 8, 1996.

Melanoma, Hematology/Oncology Fellows Board Review Lecture Series, University of Kentucky Medical Center, August 16, 1996.

A Novel Immunotherapeutic Approach for the Adjuvant Treatment of Colon Cancer, Internal Medicine Grand Rounds, University of Kentucky Medical Center, Lexington, KY, September 4, 1996.

Lymphomas, Internal Medicine Residents, University of Cincinnati Hospital, September 14, 1999.

Lymphomas, Internal Medicine Residents, University of Cincinnati Hospital, October 4, 1999.

Melanoma, Internal Medicine Residents, Univeristy of Cincinnati Hospital,Cincinnati, OH, December 9, 1999.

Lymphomas, Internal Medicine Residents, University of Cincinnati Hospital, January 6, 2000.

Cancer Research, Division of Pharmacology, Ph.D. Program, University of Cincinnati College of Medicine, January, 7, 2000.

Anti-Idiotype Cancer Vaccines, Children's Hospital Medical Center Research Foundation, Basic Scientists, January 31, 2000.

Melanoma, Internal Medicine Residents, University of Cincinnati Hospital, June 24, 1999.

Lymphomas, Internal Medicine Residency Program, University of Cincinnati, Cincinnati, OH, January 6, 2000.

Cancer Research, Division of Pharmacology, Ph.D. Program, University of Cincinnati, OH, January 7, 2000.

Anti-Idiotype Cancer Vaccines, Children's Hospital Medical Center Research Foundation, Basic Sciences, Cincinnati, OH, January 31, 2000.

Lymphoma, Internal Medicine Residency Program, University of Cincinnati, Cincinnati, OH, March 13, 2000.

Melanoma, Internal Medicine Residency Program, University of Cincinnati, Cincinnati, OH, April 14, 2000.

Non-Hodgkin's Lymphoma, Internal Medicine Residency Program, University of Cincinnati, Cincinnati, OH, June 26, 2000.

Colon Cancer, Internal Medicine Residency Program, University of Cincinnati, Cincinnati, OH, September 27, 2000

Chronic Lymphoid Leukemias, Hematology-Oncology Grand Rounds Conference, University of Cincinnati, Cincinnati, OH, September 28, 2000.

VIII ADVISING ACTIVITY

Internal Medicine Resident, University of Cincinnati College of Medicine, September, 1999.

IX. ADMINISTRATIVE ACTIVITY AND UNIVERSITY SERVICE

1989 - 1990	Search Committee for Chairman, Department of Radiation Oncology,
1989 - 1990	Search Committee for Chairman, Department of Cytogenetics, Roswell
1989 - 1990	Search Committee for Chairman, Department of Pediatrics, Roswell
1990	Head, Search Committee for Infectious Disease Specialist, Roswell Park Cancer Institute
1990 - 1991	Search Committee for Chairman, Department of Microbiology, SUNY
1989 - 1990	Radiation Safety Committee, Roswell Park Cancer Institute
1989 - 1990	Quality Assurance Committee, Roswell Park Cancer Institute
1989 - 1991	American Society of Hematology, Neoplastic Committee
1990	Head, Search Committee for Pulmonologist/Intensivist, Roswell Park
1991	Head, Search Committee for Cardiologist, Roswell Park Cancer Institute
1990 - 1991	Vice President, Medical Staff, Roswell Park Cancer Institute
1993	Head, Search Committee for Chairman of Radiation Medicine,
1989 - 1991	American Society of Clinical Oncology, Program Committee
1991 - 1992	American Association for Cancer Research, Program Committee
1992 - 1994	Clinical Immunology Society, Program Committee
1992 -present	Internal Medicine Chairman's Advisory Committee
1994 -present	Liaison Committee on Medical Education, University of Kentucky of Kentucky
1994 - 1996	Medical Center Clinical Sciences Area Advisory Committee, University of Kentucky
1996 - 1999	General Clinical Research Center Advisory Committee, University of Kentucky
1999 –present	Chair, Cancer Steering Committee, University Hospital, University of Cincinnati
1999 –present	Vontz Steering Committee, University of Cincinnati
1999 –present	Chair, Internal Advisory Committee, Barrett Cancer Center, University of Cincinnati
1999 –present	Chair, Scientific Review Committee, Barrett Cancer Center, University of Cincinnati
1999 –present	Hematology-Oncology Fellow Evaluation Committee, University of Cincinnati
1999 –present	Ohio Cancer Incidence Surveillance System Advisory Board Ohio Department of Health
1999 –present	Oncology-Hematology Care Executive Committee, University of Cincinnati

X. SPECIAL ASSIGNMENTS

Not applicable.

XI. HONORS

1971	Alpha Omega Alpha
1972	Medical degree awarded with high distinction, Wayne State University
1971	Dr. A. Ashley Rousuck Award in Internal Medicine
1972	Gordon B. Myers Award in Internal Medicine
1982	Fellow of the American College of Physicians
1982 - 1996	Editorial Board, Journal of Immunotherapy
1986 - 1990	Clinical Sciences Study Section (Subcommittee 4), Division of ResearchGrants,
1987	Distinguished Alumni Award
1987 - 1990	Associate Editor, Antibodies, Immunoconjugates and Radiopharmaceuticals
1987 -present	Associate Editor, Cancer Research
1988	Michigan Science Trailblazer
1990 - 1994	Editorial Board, Contemporary Oncology
1993 -present	Editorial Board, Journal of Clinical Immunology
1993 - 1996	Grants Review Committee for the American Cancer Society
1995 - 1997	Board of Directors, The Society for Biological Therapy
1995-present	Editorial Board, Journal of Biotherapy
1996-present	Member, Scientific Advisory Board, National Surgical Adjuvant Breast and Bowel Project
1998-present	Associate Editor, Clinical Cancer Research
1998	Faculty Research Award for Excellence in Research, University of Kentucky , Department of Internal Medicine
1998	Chairman's Award for Excellence in Research, University of Kentucky Department of Internal Medicine
2001 - present	Editorial Board, CURE: Cancer Updates, Research and Education, Dallas TX

XII. PROFESSIONAL ACTIVITY AND PUBLIC SERVICE

Societies:

1978	American College of Physicians, Member (1982, Fellow)
1980	American Society of Hematology
1980	American Association for the Advancement of Sciences
1981	American Society of Clinical Oncology
1982	American Association for Cancer Research
1982	The Society for Biological Therapy
1985 - 1987	Board of Trustees, Michigan Chapter, Leukemia Society of America
1987	Clinical Immunology Society
1987- present	Member, Leukemia Committee, Southwest Oncology Group
1991	International Society for Experimental Hematology
1994	American Cancer Society, Board of Directors, Fayette County Unit

1997- present Member, Colorectal Disease Committee, National Surgical Adjuvant Breast and
Bowel Project

1997- present Member, Melanoma Committee, Southwest Oncology Group
1998 Department of Insurance, Commonwealth of Kentucky
1999-present Member, Colorectal Committee, American College of Surgeons

XIII. SPEAKING ENGAGEMENTS

1992
Local

Advances in Systemic Treatment of Melanoma Cutaneous Malignancies, 1992 Skin Cancer Update, Scripps Clinic and Research Foundation, La Jolla, CA, February 1, 1992.

Lymphoid Malignancies: Novel Biotherapeutic Approaches, The 10th Annual Conference of Clinical Hematology and Oncology: 1992, Scripps Clinic and Research Foundation, La Jolla, CA, February 18, 1992.

Flow Cytometry and Immune Surface Markers in Hematologic Malignancies, The 10th Annual Conference of Clinical Hematology and Oncology: 1992, Scripps Clinic and Research Foundation, La Jolla, CA, February 18, 1992.

The Cytokine Network 1992: Enhancing Definitive Therapy, Scripps Clinic and Research Foundation, La Jolla, CA, May 15, 1992.

Newer Biologic Approaches to Treatment of Lymphoma and Leukemia, 18th Annual Lukes Conference, Scripps Clinic and Research Foundation, La Jolla, CA, October 15, 1992.

State

Biological Response Modifiers: Innovative Approaches to Cancer Therapy, Memorial Cancer Institute, Long Beach, CA, May 27, 1992.

Chronic Lymphocytic Leukemia: Recent Biologic and Therapeutic Advances, Grand Rounds, University of Southern California, School of Medicine, Los Angeles, CA, July 31, 1992.

Chronic Lymphocytic Leukemia in the 1990s, Medical Grand Rounds, King Drew Medical Center, Los Angeles, CA, August 4, 1992.

Chronic Lymphoid Malignancies, Berlex Corporation, San Francisco, CA, September 22, 1992.

Chronic Lymphocytic Leukemia, Grand Rounds, Western Medical Center, Santa Ana, CA, September 23, 1992.

Biologic Therapy of Cancer, Medical Grand Rounds, Mercy Hospital, San Diego, CA, November 2, 1992.

Chronic Lymphocytic Leukemia, Medical Grand Rounds, Long Beach VA Hospital, Long Beach, CA, November 19, 1992.

Chronic Lymphocytic Leukemia, Oncology Grand Rounds, University of California Irvine, Orange, CA, November 23, 1992.

Anti-Idiotype Antibodies: New Approaches to Cancer Therapy, City of Hope, Duarte, CA, December 15, 1992.

National

Chronic Lymphocytic Leukemia in the 1990s, Bethesda Naval Hospital, Bethesda, MD, June 18, 1992.

Anti-Idiotype Antibodies: Novel Therapeutic Approaches to Cancer Therapy, University of Kentucky Medical Center, Lexington, KY, August 18, 1992.

Chronic Lymphoid Malignancies, Medical Grand Rounds, Providence Hospital, Detroit, MI, August 26, 1992.

Chronic Lymphocytic Leukemia, Arizona Oncology Society, Phoenix, AZ, December 12, 1992.

International

Lymphocytic Leukemias: New Insight Into Biology and Therapy, Leukemia '92, 2nd International Course, Genoa, Italy, July 4, 1992.

1993
Local

The Staging and Treatment of Lymphomas, Kentucky Cancer Registry's Annual Workshop for Tumor Registrars, Lexington, KY, September 10, 1993.

State

Principles of Biological Response Modifiers, American Cancer Society: Cancer Nursing Course, Louisville, KY, April 21, 1993.

National

Current Approaches to Chronic Lymphoid Malignancies and Immune Therapy in Hematologic Malignancies, 11th Annual Conference Clinical Hematology and Oncology, Scripps Clinic and Research Foundation, La Jolla, CA, February 14, 1993.

Biology and Therapy of AML, AML Grant Round Lecture, University of Kansas Hospital, Kansas City, Kansas, February 24, 1993.

Chronic Lymphocytic Leukemia in the 1990's, Medical Grand Rounds, Barrett Cancer Center, University Hospital, Cincinnati, OH, May 28, 1993.

Overview of Available Cytokines and those in Development, Forum for Advances in Cytokine Therapy, Baylor University Medical, Dallas, TX, June 3, 1993.

Chronic Lymphocytic Leukemia in the 1990's, Medical Grand Rounds, Cooper Hospital, Camden, NJ, June 9, 1993.

Chronic Lymphocytic Leukemia, Medical Grand Rounds, Medical College of Pennsylvania, Philadelphia, PA, June 10, 1993.

Recombinant Human Erythropoietin Therapy in Pre-Dialysis, HIV, and Cancer Patients, Pinellas Pharmacists Society, St. Petersburg, FL, June 10, 1993.

Chronic Lymphocytic Leukemia, Medical Grand Rounds, Rex Hospital Cancer Center, Raleigh, NC, June 15, 1993.

Immunotherapy and Lymphoma, Third Annual Dorothy Inerfield Memorial Symposium, Regional Cancer Foundation, San Francisco, CA, July 10, 1993.

Chronic Lymphocytic Leukemia in the 1990's: An update, Medical Grand Rounds, Erie County Medical Center, Buffalo, NY, July 24, 1993.

Chronic Lymphocytic Leukemia in the 1990's, Medical Grand Rounds, Temple University Comprehensive Cancer Center, Philadelphia, PA, October 4, 1993

Newer Therapies for CTCL: Monoclonal Antibodies, 2nd International Symposium on Cutaneous T-Cell Lymphoma, Northwestern University Medical School, Chicago, IL, October 13, 1993.

Biology and Therapy of Lymphoid Leukemia, Medical Grand Rounds, University of New Mexico Cancer Center, Albuquerque, NM, October 19, 1993.

Combination Therapies in Lymphomas, Third International Symposium on Combination Therapies, Houston, TX, October 29, 1993.

Chair, Hematopoietic Growth Factors and Stem Cells - An Overview, Role of Cytokines in Oncology in the 1990's, Forum for Advances in Cytokine Therapy, Atlanta, GA, November 5, 1993.

Phase I Trial of Anti-Idiotype Monoclonal Antibody Vaccine Therapy for Patients with Cutaneous T-Cell Lymphoma, American Association for Cancer Research, Inc. Special Conference: Molecular Approaches to Cancer Immunotherapy, Asheville, NC, November 7, 1993.

Session Chair: Therapeutic Applications, Society for Biological Therapy of Cancer VIII, Nashville, TN, November 10, 1993.

Anti-Idiotype Vaccine Therapy in Cancer, Speaker Series, Duke Comprehensive Cancer Center, Durham, NC, November 19, 1993.

Biology and Therapy of Chronic Lymphoid Leukemia, Speaker Series, Duke Comprehensive Cancer Center, Durham, NC, November 20, 1993.

Transformation of Chronic Lymphocytic Leukemia, International Working Group for Chronic Lymphocytic Leukemia, St. Louis, MO, November 30, 1993.

Mechanisms of Oncogenesis in CLL, Future Directions in Therapy in CLL, International Workshop on Chronic Lymphocytic Leukemia, Wright City, MO, December 1, 1993.

International

American Society of Clinical Oncology, May, 1993

Chronic Lymphocytic Leukemia, The American Society of Hematology 35th Annual Meeting and Exposition, "Meet the Professor" session, St. Louis, MO, December 3, 1993.

1994
Local

Leukemia, 25th Family Medicine and Primary Care Review, University of Kentucky College of Medicine, Lexington, KY, May 24, 1994.

Leukemias and Lymphomas, Internal Medicine Board Review, University of Kentucky Medical Center, Radisson Plaza, Lexington, KY, July 13, 1994.

Advances in Gene Therapy, Kentucky Cancer Registry, 8th Annual Advanced Cancer Registrars Workshop, Lexington, September 9, 1994.

State

Chronic Lymphoid Leukemias - Advances in Biology and Therapy, Medicine Grand Rounds, James Graham Brown Cancer Center, Louisville, KY, May 19, 1994.

National

Chronic Lymphocytic Leukemia in the 1990s: An Update, Grand Rounds Lecture, University of Wisconsin Medical Center, Madison, WI, January 12, 1994.

Epoetin Alpha and 2-CdA: Advances in Clinical Research and Treatment, Faculty Update Symposium, Amelia Island, FL, January 27, 1994.

Biotherapy of Cancer, Medical Grand Rounds, William Beaumont Hospital, Royal Oak, MI, March 2, 1994.

Chronic Lymphocytic Leukemia in the 1990s: An Update, Central Ohio Society of Clinical Oncologists Conference, Columbus, OH, March 15, 1994.

Chronic Lymphocytic Leukemia in the 1990s: An Update, Medical Grand Rounds, St. Luke's Medical Center, Milwaukee, WI, March 31, 1994.

Chronic Lymphoid Leukemia: Recent Advances in Biology and Therapy. 1994 Distinguished Lecture Series, Dayton Oncology Society, Hipple Cancer Center, Dayton, OH, May 6, 1994.

CLL - New Insights in Biology and Therapy, Samuel S. Stratton Veterans Administration Medical Center, Albany, NY, May 12, 1994.

Monoclonals - Therapeutic Applications, St. Vincent's Medical Center, Jacksonville, FL, May 26, 1994.

CLL in the 1990s, Medical Grand Rounds, Roger Williams Medical Center, Providence, RI, May 31, 1994.

CLL in the 1990s: An Update, Medical Grand Rounds, University of South Alabama Medical Center, Mobile, AL, June 9, 1994.

Lymphoid Leukemia - New Concepts in Treatment, Hematology and Medical Oncology Research Conference, Cleveland Clinic, Cleveland, OH, June 24, 1994.

Indolent Non-Hodgkin's Lymphomas, Grand Rounds, Long Island Jewish Medical Center, New Hyde Park, NY, July 14, 1994.

Chronic Lymphoproliferative Disorders: Advances in Biology and Therapy, Medical Grand Rounds, Long Island Jewish Medical Center, New Hyde Park, NY, July 15, 1994.

Non-Hodgkin's Lymphoma, Roche BioScience Meeting, Phoenix, Arizona, September 20, 1994.

New Agents in the Management of Leukemia, Innovative New Therapies in Breast Cancer, Lymphoma and Leukemia Symposium, University Ireland Cancer Center, Cleveland, Ohio, September 21, 1994.

Chronic Lymphocytic Leukemia: New Insights Into Biology and Therapy, Medical Grand Rounds, M. D. Anderson Cancer Center, Houston, September 22, 1994.

Metastatic Melanoma - Current Clinical Management and Future Directions, SWOG Data Managers CE Workshop, Hyatt Regency, San Antonio, October 14, 1994.

Chronic Lymphocytic Leukemia: New Insights Into Biology and Therapy, Hematology/Oncology Grand Rounds, Harper Hospital, Detroit, October 19, 1994.

Monoclonal Antibody Approaches to Cancer Therapy, Third Annual Ingredients for Healing, Oakwood Hospital, Dearborn, MI, October 20, 1994.

International

Chronic Lymphoid Leukemias - 1994: Biology, Immunology & Therapy, British Columbia Cancer Agency, Vancouver, B.C., March 18, 1994.

Chronic Lymphocytic Leukemia in the 1990s, Grand Rounds Lecture, Cross Cancer Center, Edmonton, Alberta, March 22, 1994.

Murine Anti-Idiotype Monoclonal Antibody Induces Specific Humoral Responses to Carcino-Embryonic Antigen in Colorectal Cancer, American Society of Clinical Oncology Annual Meeting, Dallas, TX, May 17, 1994.

Active Immunity to the CEA in Patients Treated with an Anti-Idiotype Monoclonal Antibody Vaccine. Annual Meeting of Society of Biological Therapy, Silverado Country Club, Napa, CA, October 28-29, 1994.

1995
Local

Cancer Center Update, UK Hospital Auxiliary Winter Brunch, Lexington, February 24, 1995.

Cures for Cancer, WVLK Prime Line, Lexington, KY, July 7, 1995.

Leukemias and Lymphomas, Internal Medicine Board Review, University of Kentucky Medical Center, Radisson Plaza, Lexington, KY, July 12, 1995.

Overview of Cancer, Temple Adath Israel, Lexington, KY, September 8, 1995.

Research and New Findings in Breast Cancer, The Thursday Group, Lexington, October 5, 1995.

Strategies for Anti-Cancer Vaccines, American Cancer Society Research Symposium, Lexington, October 21, 1995.

State

The use of immunotherapy with vaccines, Women's Health Festival, Frankfort, September 29, 1995.

National

Anti-idiotype treatment of cancer, Carolinas Medical Center, Charlotte, NC, April 7, 1995.

Invited presentation, Leukemia Committee, Southwest Oncology Group, Phoenix, AZ, May 1, 1995.

Anti-idiotype vaccines for cancer therapy, Hem/Onc Grand Rounds, University of Cincinnati, May 12, 1995.

Invited presentation - GI Group, American Society of Clinical Oncology, Los Angeles, May 20, 1995.

Anti-idiotypic antibody vaccines: New prospects in therapy of breast cancer, American Society for Microbiology, Washington, D.C., May 25, 1995.

Flow cytometry from a clinician's perspective, Clinical Cytometry Society, Charleston, SC, August 19, 1995.

CLL - Overview and update on treatment and new strategies, American College of Physicians, Walter Reed Army Medical Center, Reston, VA, October 19, 1995.

International

CLL - Recent advances in Biology and Therapy, Grand Oncology Rounds, Tom Baker Cancer Centre, Alberta, Canada, November 7, 1995.

1996
Local

Overview on lymphoma, Amgen District Meeting, Gratz Park Inn, Lexington, KY, March 6, 1996.

National

Anti-idiotype vaccine therapy, Lung Committee, Radiation Therapy Oncology Group, New Orleans, LA, February 10, 1996.

Anti-idiotype monoclonal antibody cancer vaccines, Univ. of Virginia Cancer Center, Charlottesville, VA, March 8, 1996.

Anti-idiotype vaccines for cancer therapy, Medical Grand Rounds, Roswell Park Cancer Institute, Buffalo, NY, March 22, 1996.

Anti-idiotype vaccine therapy, Breast, Melanoma, Lung & GI Committees, Southwest Oncology Group, Burlingame, CA, April 28-29, 1996.

Submitted abstract at Joint Meeting of American Society for Biochemistry and Molecular Biology (ASBMB), American Society for Investigative Pathology (ASIP) and American Association of Immunologists (AAI), New Orleans, LA, June 2-6, 1996.

Non-Hodgkin's lymphoma and treatment of low and intermediate grade lymphomas, Regional Medical Symposium, New Orleans, LA, June 12, 1996.

Anti-idiotype vaccine therapy, Lung Committee, Radiation Therapy Oncology Group, Philadelphia, PA, July 20, 1996.

Diagnosis, recognition and treatment of high-risk melanoma, Quarterly Staff Physicians Meeting, Columbia-Davis Community Hospital, Statesville, NC, July 22, 1996.

Anti-idiotype vaccine therapy of cancer, Medical Grand Rounds, Wayne State Medical Center, Detroit, MI, July 31, 1996.

Anti-idiotype vaccine therapy, Scientific Advisory Board, National Surgical Adjuvant Breast and Bowel Project, Palm Beach, FL, September 25, 1996.

Immune flow cytometry: application to the diagnosis of lymphoma, Jaffar Annual Oncology Conference, Providence Cancer Center, Southfield, MI, September 27, 1996.

Anti-idiotype antibody vaccines that mimic CEA for patients with colorectal cancer, National Surgical Adjuvant Bowel and Breast Project Investigators Meeting, Baltimore, MD, November 8-9, 1996.

Anti-idiotype monoclonal antibodies that mimic the GD2 gangliocide and CEA, Melanoma/Sarcoma Staff Research Seminar, MD Anderson Cancer Center, Houston, TX, December 2, 1996.

Therapy of patients with anti-idiotype monoclonal antibody that mimics CEA, Cell Biology Program of Molecular Therapy Seminar Series, MD Anderson Cancer Center, Houston, TX, December 3, 1996.

International

Anti-idiotype antibody vaccine, American Society of Clinical Oncology Annual Meeting, Philadelphia, PA, May 20, 1996.

Anti-idiotype vaccine (3H1) that mimics the carcinoembryonic antigen (CEA), The Seventh International CEA/PSG Workshop, Duarte, CA, September 15, 1996.

Anti-idiotype antibody vaccine (3H1) that mimics the carcinoembryonic antigen (CEA), Third International Conference on Engineered Vaccines for Cancer and AIDS, Cambridge Symposia, Hilton Head Island, SC, October 12, 1996.

1997
National

Anti-idiotype vaccine therapy of cancer, Arkansas Cancer Research Center Seminar, Little Rock, AR, January 12, 1997.

Lymphoproliferative disorders, Southwestern Oncology Group (SWOG) Annual Meeting, Dallas TX, April 3, 1997.

Immunobiology and biologic therapy in Currigan B, American Society of Clinical Oncology (ASCO), Denver, CO, May 19, 1997.

Anti-idiotype vaccine therapy for colorectal cancer, Garden State Cancer Center, Lyndhurst, NJ, June 9, 1997.

Induction of antitumor immunity by an anti-idiotype antibody mimicking carcinoembryonic antigen, National Surgical Adjuvant Bowel and Breast Project Colorectal Committee Meeting, June 17, 1997.

Monoclonal Antibody Treatment - Colon Cancer, Stevens Cancer Center Symposium, The Scripps Clinic, La Jolla, CA, October 16, 1997.

Anti-idiotype vaccine therapy for colorectal cancer, University of South Carolina School of Medicine, Columbia, South Carolina, October 31, 1997.

Anti-idiotype vaccine therapy for malignant melanoma, Tumor Conference, Comprehensive Cancer Research Group, Salick Health Care, Miami, Florida, November 12, 1997.

Anti-idiotype vaccine therapy for breast cancer, CALGB Fall Group Meeting, University of Chicago, Orlando, Florida, November 22, 1997.

Anti-idiotype vaccine therapy for colorectal cancer, Cancer Institute of New Jersey, New Brunswick, New Jersey, December 17, 1997.

1998
Local

Management of low grade lymphoma, Emerging Trends in the Treatment of Lymphoma, Continuing Medical Education Program, Hilton Suites of Lexington Green, Lexington, Kentucky, June 13, 1998.

National

Anti-idiotype vaccine that mimics the carcinoembryonic antigen, Albert Einstein College, Bronx, New York, January 29, 1998.

Immunotherapy for Colon Cancer (CEA Idiotype), Regional Cancer Center Consortium for Biological Therapy of Cancer, Buffalo, New York, February 21, 1998.

Anti-idiotype vaccine therapy of colorectal cancer targeting the carcinoembryonic antigen, University of Cincinnati, Barrett Cancer Center, Cincinnati, Ohio, March 16, 1998.

Monoclonal antibodies for cancer therapy, Oncology Symposium, Carl & Dorothy Bennett Cancer Center, Stamford Hospital, Stamford, Connecticut, April 22, 1998.

Anti-idiotype vaccine therapy of colorectal cancer mimiking CEA, Grand Rounds Series, Ohio State University Comprehensive Cancer Center, Arther G. James Cancer Hospital and Research Institute, Columbus, Ohio, April 24, 1998.

Idiotype vaccines for colorectal cancer, Vaccine Research Workshop, Southwest Oncology Group Meeting (SWOG), Atlanta, Georgia, April 24, 1998.

Immune responses in advanced melanoma patients immunized with an anti-idiotype (Id) antibody mimicking disialoganglioside GD2. American Society of Clinical Oncology (ASCO), Los Angeles, CA, May 18, 1998.

Clinical and immune responses in surgically resected colorectal cancer (CRC) patients treated with an anti-idiotype (Id) monoclonal antibody that mimics carcinoembryonic antigen (CEA) with or without 5-fluorouracil (5-FU). American Society of Clinical Oncology (ASCO), Los Angeles, CA, May 18, 1998.

Immune responses in patients with breast cancer treated with an anti-idiotype antibody that mimics the human milk fat globule (HMFG) antigen. American Society of Clinical Oncology (ASCO), Los Angeles, CA, May 18, 1998.

Immune phenotype of lymphomas and leukemias, Huntington Blood Clug, Marshall University, Department of Medicine, Huntington, West Virginia, June 1, 1998.

Classification of lymphomas and novel new therapies, Medical Grand Rounds, Cabell Huntington Hospital, Marshall University, Huntington, West Virginia, June 2, 1998.

Phase II study of Doxil in the treatment of patients with refractory/relapsed NHL, Doxil Advisory Panel Meeting, Ritz-Carlton Amelia Island, Florida, June 6, 1998.

Novel antibody therapies for cancer, Medical Grand Rounds, Rush Presbyterian St. Lukes Medical Center, Chicago, Illinois, June 24, 1998.

Novel approaches to antibody therapy for cancer, Dinner Lecture, Akron General Cancer Center, Akron, Ohio, June 30, 1998.

Anti-idiotype monoclonal antibody vaccine that mimics the carcinoembryonic antigen: The novel therapeutic approach to colorectal cancer, Cancer Therapy Research Center Burton & Miriam Grossman, San Antonio, Texas, August 13, 1998.

Novel new antibody approaches to cancer therapy, Tumor Board, Community Hospital East, Indianapolis, Indiana, September 22, 1998.

Cancer vaccines, Oncology Program, Akron General Medical Center, Akron, Ohio, October 14, 1998.

Anti-idiotype antibody vaccine mimicing carcinoembryonic antigen, Chemotherapy Foundation Symposium XVI Innovative Cancer Therapy for Tomorrow, Mount Sinai School of Medicine, New York, New York, November 11, 1998.

Anti-idiotype vaccine that mimics CEA for therapy of colon cancer, ECOG GI Committee, Northwestern University Medical School, Miami, Florida, November 21, 1998.

Excellent responses to sequential fludarabine (F) followed by cyclophosphamide (C), mitoxantrone (M), vincristine (V), and prednisone (P) (CNOP) in previously untreated patients with follicle center lymphoma, grade I and II, The 40th Annual Meeting of the American Society of Hematology, Miami, Florida, December 7, 1998.

International

Clinical and immune responses in colorectal cancer (CRC) patients treated with an anti-idiotype (Id) monoclonal antibody (mAb) that mimics carcinoembryonic antigen (CEA), XVII International Cancer Congress, Rio de Janeiro, Brazil, August 24-28, 1998.

1999
Local

Anti-Idiotype Vaccine Approach to the Treatment of Colorectal Cancer, Medicine Grand Rounds, University of Cincinnati, Cincinnati, OH, February 24, 1999.

Vaccine Approaches to the Treatment of Colorectal Cancer, Environmental Health Seminar, University of Cincinnati College of Medicine, Cincinnati, OH, April 14, 1999.

Anti-Idiotype Vaccine Approach to Cancer, Head & Neck Cancer: Conference, the Barrett Cancer Center, University of Cincinnati, Cincinnati, OH, June 19, 1999.

Cancer Research Update, Focus Research Breakfast, The University of Cincinnati Foundation, Cincinnati, OH, June 23, 1999.

Future Direction for Cancer Research at the Barrett Cancer Center, Ameican Cancer Society Research Reception, Cincinnati, OH, September 16, 1999.

Anti-Idiotype Antibody Vaccines: Novel Approach to Cancer Immunotherapy, Molecular to the Bedside, University of Cincinnati College of Medicine, Cincinnati, OH, September 30, 1999.

Monoclonal Antibody Anti-Idiotype Vaccine Therapy, Hematology-Oncology Grand Rounds, University of Cincinnati, Cincinnati, OH, October 1, 1999.

New Approaches to the Treatment of Lymphoma, Cincinnati Society of Internal Medicine, University of Cincinnati, Cincinnati, OH, October 4, 1999.

Anti-Idiotype Vaccine Therapy of Melanoma, University of Cincinnati, Cincinnati, OH, The Barrett Cancer Center, October 26, 1999.

Lymphoma, Wellness Community, Cincinnati, OH, November 6, 1999.

Ensuring Quality Cancer Care, The Central Ohio River Valley Cancer Alliance, Cincinnati, OH, November 30, 1999.

National

Breast Cancer: Clinical Issues, International Cancer Alliance Breast Cancer Symposium, West Palm Beach, FL, January 23, 1999.

Immunologic Approaches to Malignant Melanoma, First Annual International Melanoma Conference, Miami Beach, FL, February 13, 1999.

Monoclonal Antibodies in the Treatment of Breast Cancer, 22nd Annual Gold Coast Conference: Breast Cancer, West Palm Beach, FL, February 23, 1999.

Anti-Idiotype Vaccines: Novel Approach for the Therapy of Colorectal Cancer, Annual Cancer Conference, Swedish Medical Center, Seattle, WA, April 23, 1999.

Colorectal Cancer as a Model for Immunotherapy, Southwest Oncology Group Conference, Phoenix, AZ, April 28 – May 2, 1999.

Anti-Idiotype Antibody Vaccines, Targeted Cellular Toxicity: The VIth International Conference on Bispecifics Antibodies Conference, Asilomar Conference Center, Pacific Grove, CA, July 30, 1999.

Targeted Therapies in the Treatment of Lymphoma, University of Louisville, Louisville, KY, August 5, 1999.

Lymphoma, Educational Overview, SuperGen Meeting, Phoenix, AZ, August 16, 1999.

Anti-Idiotype Monoclonal Antibody Vaccine that Mimics the Carcinoembryonic Antigen, 12th International Conference on Monoclonal Antibody Immunoconjugates for Cancer, San Diego, CA, October 14 – 16, 1999.

2000
Local

Anti-Idiotype Cancer Vaccines, The Children's Hospital Research Foundation Immunotherapy Conference, Cincinnati, OH, January 31, 2000.

Anti-idiotype Vaccine that Mimics CEA: Novel therapeutic approach to colon cancer treatment. Case Western University, Ireland Cancer Center, Blood Club Seminar, Cleveland, OH, February 25, 2000.

The Barrett Cancer Center in the New Millennium. UC Board of Trustees, University of Cincinnati, Cincinnati March 29, 2000.

Anti-idiotype Vaccine that Mimics the Carcinoembryonic Antigen. Dept. of Pathology and Laboratory Medicine, University of Cincinnati, Cincinnati, OH April 20, 2000.

Cancer Vaccines. Sabin 40th Annual Anniversary Celebration, University of Cincinnati, Cincinnati, OH April 28, 2000.

The Barrett Cancer Center and the New Millennium. UC Medical Center Orientation, Cincinnati, OH May 4, 2000.

Non-Hodgkin's Lymphoma. Miami Valley Hospital Tumor Board, Dayton, OH May 5, 2000.

Colorectal Cancer: Molecular Genetics and Therapeutic Advances. University-Wide Clinical Pathology Conference, Cincinnati, OH May 10, 2000.

Vaccine Therapies of Malignant Melanoma. Hematology-Oncology Grand Rounds, University of Cincinnati, Cincinnati, OH. May 26, 2000.

Welcome and Introduction, Cancer Survivor's Day, University of Cincinnati, Cincinnati, OH, June 4, 2000.

Vaccine Approaches to the Adjuvant Treatment of Colorectal Cancer. The Barrett Cancer Center and University of Cincinnati Annual Cancer Conference. Cincinnati, OH June 17, 2000.

Chronic Lymphoid Leukemias. Hematology-Oncology Grand Rounds Conference, University of Cincinnati, Cincinnati, OH. September 29, 2000.

Overview of Immune Flow Cytometry of Leukemias and Lymphomas. The Barrett Cancer Center, University of Cincinnati College of Medicine, Cincinnati, OH. October 7, 2000.

National

Anti-Idiotype Antibodies Directed Against Gangliosides. Melanoma at the Millennium Conference, Phoenix, AZ, February 17, 2000

Clinical and Immune Responses in Resected Colon Cancer patients Treated with Anti-Idiotype Monoclonal Antibody Vaccine that mimics the CarcinoembryonicAntigen. International Conference on Advances in Cancer Immunotherapy, Princeton, NJ, March 2 - 4, 2000.

Clinical Trials of Immunotherapeutics and Immunologic Monitoring. American Association for Cancer Research, April 3 – 4, 2000.

Cancer Vaccines. 2000 American Society of Clinical Oncology, New Orleans, LA. May 19 – 22, 2000.

An Update on Cancer Vaccines. 12th Annual Western North Carolina Cancer Conferennce, Asheville, North Carolina, October 27, 2000.

Rubitecan: An Effective New Therapy in Pancreatic Cancer. Chemotherapy Foundation Symposium XVIII, New York City, New York, November 8, 2000.

Vaccine in the Treatment of GI Malignancies. Gastrointestinal Cancer Research Conference 2000, Orlando, Florida, November 16 – 18, 2000.

International

Clinical and immune responses in resected colon cancer patients treated with anti-idiotype monoclonal antibody vaccine that mimics the carcinoembryonic antigen. 2nd Annual Walker's Cay Colloquium, Albert B. Sabin Vaccine Institute, Abaco, Bahamas, March 8 – 12, 2000.

2001
Local

National

Anti-Idiotype Antibody that Mimics Carcinoembryonic Antigen: Novel new Approach to Colon Cancer Immunotherapy. The Molecular Medicine of Colorectal Cancer, Keystone Symposia on Molecular and Cellular Biology, Taos, New Mexico, February 1 – 2, 2001.

Expanding Options in the Treatment of Non-Hodgkin's Lymphoma. Medical City Tumor Conference, Medical City Dallas Hospital, Dallas, TX. March 21, 2001.

Monoclonal Antibodies in Combination with Chemotherapy for the Treatment of Non-Hodgkin's Lymphoma. IDEC Pharmaceuticals Corporation, Dallas, TX. March 21, 2001.

CeaVac, a Novel Anti-Idiotype Antibody Vaccine Therapy for Colon Cancer. American Cancer Society, 43rd Annual Science Writers Seminar, Laguna Beach, CA. April 22 – 25, 2001.

International

XIV. RESEARCH AND/OR CREATIVE PRODUCTIVITY

1. Publications

A. Peer-Reviewed Manuscripts:

1. Foon KA, Wahl SM, Oppenheim JJ and Rosenstreich DL: Serotonin-induced production of a monocy

2. Sher NA, Foon KA, Fishman ML and Brown T: Demonstration of monocyte chemotactic factors in the aqueous humor during experimental immunogenic uveitis in the rabbit. Infect Immun 13:1110-1116, 1976.

3. Sher ND, Douglas DJ, Mindrup E, Minaii LA and Foon KA: Macrophage migration inhibition factor activity in the aqueous humor during experimental corneal xenograft and allograft rejection. Am J Ophthalmol 82:858-865, 1976.

4. Foon KA, Yuen K, Ballintine E and Rosenstreich D: Analysis of the systemic corticosteroid sensitivity of patients with primary open angle glaucoma. Am J Ophthalmol 83:167-173, 1977.

5. Foon KA, Naiem F, Yale C and Gale RP: Acute myelogenous leukemia: Morphologic subclass and response to therapy. Leuk Res 3:171-173, 1979.

6. Foon KA, Billing RJ and Terasaki PI: Dual B and T markers in acute and chronic lymphocytic leukemia. Blood 55:16-20, 1980.

7. Billing RJ, Clark BM, Koeffler P, Foon KA and Terasaki PI: Acute myelocytic leukemia heteroantisera. Clin Immunol Immunopathol 16:202-210, 1980.

8. Foon KA, Yale C, Clodfelter K and Gale RP: Effect of posttreatment hepatitis on survival of patients with acute myelogenous leukemia. JAMA, 244:1806-1807, 1980.

9. Foon KA, Fitchen JH, Billing RJ, Belzer MB, Terasaki PI and Cline MJ: An antithymocyte serum non-cytotoxic to myeloid progenitor cells: Candidate serum for prevention of graft-versus-host disease in bone marrow transplantation. Clin Immunol Immunopathol 16:416-422, 1980.

10. Foon KA, Billing RJ, Terasaki PI and Cline MJ: Immunologic classification of acute lymphocytic leukemia: Implications for normal lymphoid differentiation. Blood 56:1120-1126, 1980.

11. Foon KA, Herzog P, Billing R, Terasaki PI and Feig S: Immunologic classification of childhood acute lymphocytic leukemia. Cancer 47:280-284, 1981.

12. Foon KA, Naeim F, Saxon A, Stevens R and Gale RP: Leukemia of T-helper lymphocytes: Clinical and functional characterization. Leuk Res 5:1-10, 1981.

13. Foon KA, Billing RJ, Fitchen JH, Belzer MB, Drew SI and Terasaki PI: An antigen expressed by cells of the myelo-monocytic lineage. Am J Hematol 10:259-267, 1981.

14. Belzer M, Fitchen JH, Ferrone S, Foon KA, Billing RJ and Golde DW: Expression of HLA-DR antigen on human erythroid progenitor cells as determined by monoclonal anti-DR antibodies and heteroantiserum. Clin Immunol Immunopathol 20:111-115, 1981.

15. Gale RP, Foon KA, Cline MJ and Zighelboim J: Intensive chemotherapy for acute myelogenous leukemia. Ann Intern Med 94:753-757, 1981.

16. Fitchen JH, Foon KA and Cline MJ: The antigenic characteristics of hematopoietic stem cells. N Engl J Med 305:17-25, 1981.

17. Foon KA, Zighelboim J, Yale C and Gale RP: Intensive chemotherapy is the treatment of choice for elderly patients with acute myelogenous leukemia. Blood 58:467-470, 1981.

18. Foon KA, Filderman A and Gale RP: Histiocytic lymphoma following resolution of sarcoidosis. Med Pediatr Oncol 9:325-331, 1981.

19. Hoffman F, Foon KA, Smith D, Kransler J, Ciciarelli J and Billing R: Functional properties of subsets of T lymphocytes defined by special antigens. Clin Exp Immunol 44:476-484, 1981.

20. Hocking WG, Billing R.J, Foon KA and Golde DW: Human alveolar macrophages express DR antigens. Blood 58:1040-1042, 1981.

21. Linker-Israeli M, Billing RJ, Foon KA and Terasaki PI: Monoclonal antibodies reactive with acute myelogenous leukemia cells. J Immunol 127:2473-2477, 1981.

22. Billing R, Terasaki PI, Sugich L and Foon KA: Detection of differentiation antigens by use of monoclonal antibodies. J Immunol Methods 47:289-294, 1981.

23. Schroff RW, Foon KA, Billing RJ and Fahey JL: Immunologic classification of lymphocytic leukemias based on monoclonal antibody-defined cell surface antigens. Blood 59:207-215, 1982.

24. Foon KA and Haskell CM: Inadvertent overdose with lomustine (CCNU) followed by hematologic recovery. Cancer Treat Reports 66:1241-1241, 1982.

25. Foon KA and Gale RP: Controversies in the therapy of acute myelogenous leukemia. Am J Med 72:963-979, 1982.

26. Foon KA, Schroff RW and Gale RP: Cell surface markers on leukemia and lymphoma cells: Recent advances. Blood 60:1-19, 1982.

27. Billing RJ, Foon KA and Linker-Israeli M: The immunological classification of leukemia based on a rapid microcytoxicity test. Clin Exp Immunol 49:142-148, 1982.

28. Schroff RW and Foon KA: Heterogeneity in a lymphoid tumor: Co-expression of T and B surface markers. Blood 60:373-380, 1982.

29. Foon KA, Schroff RW and Fliegel S: Monoclonal antibody characterization of plasmacytoma cells associated with T lymphocytes with a suppressor phenotype. Clin Immunol Immunopathol 25:59-66, 1982.

30. Foon KA, Bernhard MI and Oldham RK: Monoclonal antibody therapy: Assessment by animal tumor models. J Biol Response Mod 1:277-304, 1982.

31. Sherwin SA, Knost JA, Fein S, Abrams PG, Foon KA, Ochs JJ, Schoenberger C, Maluish AE and Oldham RK: A multiple dose phase I trial of recombinant leukocyte A interferon in cancer patients. JAMA 248:2461-2466, 1982.

32. Key ME, Bernhard MI, Hoyer LC, Foon KA, Oldham RK and Hanna MG: Guinea pig line 10 hepatocarcinoma model for monoclonal antibody serotherapy: *In vivo* localization of a monoclonal antibody in normal and malignant tissues. J Immunol 120:1451-1457, 1983.

33. Sherwin SA, Mayer D, Ochs JJ, Abrams PG, Knost JA, Foon KA, Fein S and Oldham RK: Recombinant leukocyte A interferon in advanced breast cancer: Results of a Phase II efficacy trial. Ann Intern Med 98:598-602 1983.

34. Bernhard MI, Foon KA, Oeltmann TN, Key ME, Hwang KM, Clarke CG, Christensen WL, Hoyer LC, Hanna MG and Oldham RK: Guinea pig line 10 hepatocarcinoma model: Characterization of monoclonal antibody and *in vivo* effect of unconjugated antibody and antibody conjugated to diptheria toxin A chain. Cancer Res 43:4420-4428, 1983.

35. Bernhard MI, Hwang KM, Foon KA, Keenan A, Kessler R, Frincke, Tallum DJ, Hanna MG, Peters L and Oldham RK: Localization of ^{111}In- and ^{125}Io-labeled monoclonal antibody in guinea pigs bearing line 10 hepatocarcinoma tumors. Cancer Res 43:4429-4433, 1983.

36. Foon KA, Smalley RV, Riggs CW and Gale RP: The role of immunotherapy in acute myelogenous leukemia. Arch Intern Med 143:1726-1734, 1983.

37. Knost JA, Sherwin SA, Abrams PG, Ochs JJ, Foon KA, Williams R, Tuttle R and Oldham RK: The treatment of cancer patients with human lymphoblastoid interferon: A comparison of two routes of administration. Cancer Immunol Immunother 15:148-155, 1983.

38. Abrams PG, Knost JA, Clarke G, Wilburn S, Oldham RK and Foon KA: Determination of the optimal human cell lines for development of human hybridomas. J Immunol 131:1201-1204, 1983.

39. Foon KA, Buescher S, Kimball ES, Huang LC, Stevenson HC, Clarke G, Gregoria T and Harley JB: Monoclonal antibody to human eosinophils recognizing 95 kD surface membrane antigen. Hybridoma 2:393-402, 1983.

40. Stevenson HC, Foon KA, Kanapa DJ, Favilla T, Beman J and Oldham RK: The potential value of cytapheresis for adoptive immunotherapy of cancer patients. Plasma Ther Transfus Technol 5:237-250, 1984.

41. Hwang JM, Foon KA, Cheung PH, Pearson JW and Oldham RK: Selective antitumor effect on L10 hepatocarcinoma cells of a potent immunoconjugate composed of the A chain of abrin and a monoclonal antibody to a hepatoma-associated antigen. Cancer Res 44:4578-4586, 1984.

42. Foon KA, Mutsuyasu RT, Schroff RW, McIntyre RE, Champlin R and Gale RP: Immune deficiency in young males with hepatitis-associated severe aplastic anemia. Ann Intern Med 100:657-662, 1984.

43 Oldham RK, Morgan AC, Woodhouse CS, Schroff RW, Abrams PG and Foon KA: Monoclonal antibodies in the treatment of cancer: Preliminary observations and future prospects. Med Oncol Tumor Pharmacother 1:51-62, 1984.

44. Abrams PG, Ochs JJ, Giardina SL, Morgan AC, Wilburn SB, Wilt AR, Oldham RK and Foon KA: Production of large quantities of human immunoglobulin in the ascites of athymic mice: Implication for the development of anti-human idiotype monoclonal antibodies. J Immunol 132:1611-1613, 1984.

45. Stevenson HC, Ochs JJ, Halverson L, Oldham RK, Sherwin SA and Foon KA: Recombinant alpha interferon in retreatment of two patients with pulmonary lymphoma. Dramatic responses with resolution of pulmonary complications. Am J Med 77:355-358, 1984.

46. Fer MF, Beman J, Stevenson HC, Maluish A, Moratz C, Foon KA, Herberman RB, Oldham RK, Terman DS, Young JB and Daskal Y: A trial of autologous plasma perfusion over protein A in patients with breast cancer. J Biol Response Mod 3:352-358, 1984.

47. Champlin R, Jacobs A, Gale RP, Boccia R, Elashoff R, Foon KA and Zighelboim J: Prolonged survival in acute myelogenous leukemia without maintenance chemotherapy. Lancet 1:894-896, 1984.

48. Schroff RW, Farrell MM, Klein RA, Oldham RK and Foon KA: T65 antigen modulation in a phase I monoclonal antibody trial with chronic lymphocytic leukemia patients. J Immunol 133:1641-1648, 1984.

49. Foon KA, Neubauer RH, Wikstrand CJ, Schroff RW, Rabin H and Seeger RC: Human Thy-1 antigen: Distribution on human and non-human primate hematopoietic cells. J Immunogenet 11:233-244, 1984.

50. Foon KA, Schroff RW, Bunn RA, Mayer D, Abrams PG, Fer MF, Ochs JJ, Bottino GC, Sherwin SA, Herberman RB and Oldham RK: Effects of monoclonal antibody therapy in patients with chronic lymphocytic leukemia. Blood 64:1085-1094, 1984.

51. Oldham RK, Foon KA, Morgan AC, Woodhouse C, Schroff RW, Abrams PG, Fer MF, Schoenberger C, Farrell M, Kimball E and Sherwin SA: Monoclonal antibody therapy of malignant melanoma: *In vivo* localization in cutaneous metastasis after intravenous administration. J Clin Oncol 2:1235-1244, 1984.

52. Reynolds CW and Foon KA: T-lymphoproliferative disease and related disorders in man and experimental animals. A review of the clinical, cellular and functional characteristics. Blood 64:1146-1158, 1984.

53. Fer MF, Bottino GC, Sherwin SA, Hainesworth JD, Abrams PG, Foon KA and Oldham, RK: Atypical tumor lysis syndrome in a patient with T-cell lymphoma following recombinant interferon therapy. Am J Med 77:953-956, 1984.

54. Bunn PA, Foon KA, Idhe DC, Winkler CF, Zeffren J, Sherwin SA and Oldham RK: Recombinant leukocyte A interferon: An active agent in advanced cutaneous T-cell lymphoma. Ann Intern Med 101:484-487, 1984.

55. Stevenson HC, Kimball ES, Buescher S, Clarke G and Foon KA: Monoclonal antibody to human monocytes and granulocytes: Isolation of membrane antigens and lack of effect on leukocyte functions *in vitro*. Hybridoma 3:247-261, 1984.

56. Foon KA, Sherwin SA, Abrams PG, Longo DL, Fer MF, Stevenson HC, Ochs JJ, Bottino GC, Schoenberger CS, Zeffren J, Jaffe ES and Oldham RK: Treatment of advanced non-Hodgkin's lymphoma with recombinant leukocyte A interferon. N Engl J Med 311:1148-1152, 1984.

57. Morgan AC, Woodhouse CS, Knost JA, Abrams PG, Clarke GC, Arthur LO, McIntrye R, Ochs JJ, Foon KA, Hanna MG and Oldham RK: Monoclonal antibodies to human colorectal tumor-associated antigens: Improved elicitation and subclass restriction. Hybridoma 3:233-245, 1984.

58. Sherwin SA, Foon KA, Oldham RK, Abrams PG, Heyman MR, Ochs JJ, Watson R and Maluish A: A preliminary phase I trial of partially purified interferon-gamma (IFN-gamma) in patients with disseminated cancer. Biol Response Mod 3:599-607, 1984.

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64. Gale RP and Foon KA: Chronic lymphocytic leukemia: Recent advances in biology and treatment. Ann Intern Med 103:101-120, 1985.

65. Giardina SL, Schroff RW, Woodhouse CS, Golde DW, Oldham RK, Cleary ML, Sklar J, Pritikin N and Foon KA: Detection of two malignant B-cell clones in a single patient using anti-idiotype monoclonal antibodies and immunoglobulin gene rearrangement. Blood 66:1017-1021, 1985.

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146. Bhatnagar A, Lowy A, Rohatgi N, Chatterjee M, Bard V, Baral R, Saha A, Das R. CeaVac anti-idiotype (Anti-Id) monoclonal antibody (Mab) therapy of colon cancer patients: comparison of different routes of administration using an alugel preparation of vaccine. *Proc of ASCO.* 5/01.

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John W, Foon KA. CeaVac anti-idiotype (Anti-Id) monoclonal antibody (Mab) treatment for resected colorectal cancer (CRC): results of a phase II trial. *Proc. of ASCO.* 5/01.

8. Other (Videos)

1. Foon KA: Interferons. Hoffmann La Roche, 1986.

2. Foon KA: Antibody Structure and Function. NeoRx, 1988.

3. Foon KA: Therapy of Acute Leukemia: Recent Progress and Future Directions. Wyeth, 1988.

4. Foon KA: Cancer Vaccine Therapy: New Approaches, Video Journal of Oncology, Secaucus, NJ 1993.

Grant Activity
Inactive Funded Grants

Louis Sklarow Memorial Fund, "Monoclonal Antibodies for B-Cell Lymphomas," Kenneth A. Foon, M.D., Principal Investigator, 7/1/86 - 6/31/87, $42,000 (total cost).

NIH 1 RO1 CA43212-01, "Mechanisms of Interferon Action in Hairy-Cell Leukemia," Kenneth A. Foon, M.D., Principal Investigator, 9/30/86 - 6/30/89, $173,960 (total direct cost).
NIH PO1 CA42768, "Radiopharmaceutical Diagnosis and Treatment of Cancer," Subproject: "Preclinical and Clinical Treatment with Monoclonal Antibodies to B-Cell Lymphomas," Kenneth A. Foon, M.D., Principal Investigator, 9/30/87 - 2/28/89, $265,803 (total direct cost).

"A Phase I/II Study of High-Dose, Continuous-Infusion Recombinant Human Interleukin-2 with Non-Small Cell Lung Cancer and Resistant Lymphoma," Kenneth A. Foon, M.D., Principal Investigator, Hoffmann La Roche, Inc., 10/1/88 - 9/30/89, $50,000 (total cost).

"A Phase I/II Clinical Investigation to Evaluate the Safety and Efficacy of Continuous Infusions of Recombinant Interleukin-2 and Phenylalanine Methyl Ester Pretreated Cells in Patients with Unresectable and/or Metastatic Melanoma and Renal Cell Cancer," Kenneth A. Foon, M.D., Principal Investigator, Dupont Corporation, 1/1/89 - 12/31/90, $270,000 (total cost).

NIH RO1 CA47860, "Idiotype Approach to Therapy of Human T-Cell Leukemia," Malaya Chatterjee, Ph.D., Principal Investigator, Kenneth A. Foon, M.D., Co-Investigator (10%), 4/1/89 - 3/31/92, $381,495 (total direct cost).

"Therapy of Renal Cell Carcinoma and Malignant Melanoma with Interleukin-2," Kenneth A. Foon, M.D., Principal Investigator (5%), Hoffmann La Roche, Inc., 6/1/90 - 5/31/91, $39,000 (total cost).

NIH 1PO1 CA4767-03 (Consortium), "Monoclonal Antibody Therapy of Breast Cancer," R. Ceriani, M.D., Program Director; "^{111}Indium-Labeled Monoclonal Antibody Imaging of Metastatic Breast Cancer," Kenneth A. Foon, M.D., Principal Investigator (5%), 1/2/91 - 8/31/91, $96,025 (total direct cost).

Buffalo Foundation Grant 857-0484A, "Feasibility Study of Anti-Idiotype Monoclonal Antibody Therapy for Patients with Cutaneous T-Cell Lymphoma," Kenneth A. Foon, M.D., Principal Investigator (5%), 3/1/91 - 2/29/92, $7,000 (total cost).

NIH 1PO1 CA58880-01A2 (Program Project Grant), "Monoclonal Antibody Therapy for GI Cancer," Kenneth A. Foon, M.D., Principal Investigator (20%), 9/1/91 - 8/31/94, $900,000 (total direct cost).

NIH RO1 CA54321-01 (Consortium), "Structure-Function of Tumor-Anti-Idiotype Antibodies," Heinz Köhler, M.D., Ph.D., Principal Investigator; "Generation of Tumor-Anti-Idiotypic Antibodies," Malaya Chatterjee, Ph.D., Principal Investigator, Kenneth A. Foon, M.D., Co-Investigator (10%), 7/1/91 - 6/30/94, $130,902 (total direct cost).

Share Foundation, "Phase Ib Study of Monoclonal Anti-Idiotype Antibody Therapy for Patients with Metastatic Melanoma," 1/1/93 - 12/31/95, $125,000 (total cost).

Ortho Pharmaceutical Corp. - Treatment of previously untreated chronic lymphocytic leukemia, 1994-95, $50,000.

Tobacco & Health, Anti-Idiotype Vaccine for Human Small Cell Lung Carcinoma, 7/1/94-6/30/95, $79,900 (total direct cost).

NCI 1PO1 CA57165-04 (Program Project Grant), "Monoclonal Antibody Therapy of GI Cancer", Kenneth A. Foon, M.D., Principal Investigator. Project 1. "Generation of Anti-Idiotype Tumor

Vaccines", M. Chatterjee, Ph.D., Principal Investigator. 9/30/91 - 8/31/95, $768,027 (direct cost), $126,221 (indirect cost).

Berlex, Treatment of previously untreated low grade follicular lymphoma, Kenneth A. Foon, M.D., Principal Investigator, 1994-95, $51,000.

NCI 5U10 CA46136-07, Southwest Oncology Group Clinical Study, Kenneth A. Foon, M.D., Principal Investigator, 1/1/88 - 12/31/97, $507,164 (direct cost), $244,266 (indirect cost).

NIH R01 CA60000-02, Anti-Idiotype Vaccine for Breast Cancer, Kenneth A. Foon, M.D., Principal Investigator, 12/1/94 - 11/30/97, $477,406 (total direct cost), $233,929 (indirect cost).

P20-, Planning Grants for Prospective Cancer Centers, Kenneth A. Foon, M.D., Principal Investigator, 8/1/95 - 7/30/97, $350,000 (direct cost), $171,500 (indirect cost).

NCI R03 CA72468-01, Comparison of Alum and QS-21 Based Anti-Idiotype Vaccines, Kenneth A. Foon, M.D., Principal Investigator, 12/1/96 - 11/30/98, $147,000 (direct and indirect cost).

NCI U01 CA65748-01, New Therapeutic Approaches to Breast Cancer, Kenneth A. Foon, M.D., Principal Investigator, 12/1/94 - 11/30/98, $842,019 (direct cost), $412,589 (indirect cost).

NIH NCI U01CA65748, "New Therapeutic Approaches to Breast Cancer", Principal Investigator, Kenneth A. Foon, M.D., 1/1/95 – 12/31/99.

NIH NCI R03 CA68629, "Comparison of Alum and QS-21 Based Anti-Id Vaccione", Principal Investigator Kenneth A. Foon, M.D., 11/01/96 – 10/31/99

NIH NCI R01 CA72773-03, "Immunotherapy of Cancer with Anti-Id Based DNA Vaccines", Principal Investigator, Sunil K. Chatterjee, Ph.D., 10/01/99- 12/31/99.

Lucille P. Markey Charitable Trust, Research Program Grant, Kenneth A. Foon, M.D., Principal Investigator, 1/2/95 - 2/15/99, $1,900,000 (total direct cost).

NIH R03 CA79401-01, Anti-Idiotype Vaccine with IL-2 for Advanced Melanoma, Kenneth A. Foon, M.D., Principal Investigator,11/1/98 - 10/30/00, $145,646 (total direct and indirect cost).

Amgen, High Grade Lymphoma, Kenneth A. Foon, M.D., Principal Investigator, 2/1/95 - 2/1/99, $15,000 ($11,910 direct costs, $3,090 indirect cost).
NIH R01 CA72018-01, Ganglioside GD2 as Target for Immunotherapy in Melanoma, Kenneth A. Foon, M.D., Co-Investigator, 8/1/96 - 6/30/01, $1,142.854 (direct cost), $1,679,995 (total cost).

Active Funded Grants

Titan Pharmaceutical, Inc., Anti-Idiotype Antibody Vaccines, Kenneth A. Foon, M.D., Co-Principal Investigator, 7/1/96 - 6/30/01, $1,750,000 (total direct cost). (Malaya Chatterjee, Ph.D., Co-Principal Investigator).

NIH RO1 CA86025-01, "Anti-Idiotype Vaccine Therapy of Human Colorectal Cancer", Kenneth A. Foon, M.D., Co-Investigator, 9/01/00 – 8/31/03, $1,818,570.00 (total direct cost). (Malaya Chatterjee, Ph.D., Principal Investigator).

NIH R01 CA72018-01, Ganglioside GD2 as Target for Immunotherapy in Melanoma, Kenneth A. Foon, M.D., Principal Investigator, 9/01/01 – 8/30/06, $1,250,000.00 (total direct cost). (Malaya Chatterjee, Ph.D., Co-Investigator).

NIH R01 CA91878-01 HER2/Neu: A Target for Cancer Immunology. Kenneth A. Foon, M.D., Co-Investigator, 9/1/01 – 8/30/06, $1,125,000.00 (total direct cost). (Malaya Chatterjee, Ph.D., Investigator).

Grants Pending:

None.

Patents

Tri-Gem (1A7)
Patent Number: 5,612,030
Date of Patent: 3/18/97
"Anti-idiotype monoclonal antibody 1A7 and use for the treatment of melanoma and small cell carcinoma"

TriAb (11D10)
Pending Serial Number: 08/766,350
Date Filed: 12/13/96
"Murine monoclonal anti-idiotype antibody 11D10 and methods of use thereof"

CeaVac (3H1)
Pending Serial Number: 08/579940
Date Filed: 12/28/95 (whole antibody)
"Murine monoclonal anti-idiotypic antibody 3H1"

Pending Serial Number: 08/579916
Date Filed: 12/28/95
"Recombinant monoclonal anti-idiotypic antibody 3H1 sequences relating to human carcinoembryonic antigen"

1008 ORAL PRESENTATION, SUN, 12:45 PM - 4:45 PM

Trigem Anti-Idiotype (Anti-Id) Monoclonal Antibody (MAb) Treatment for Stage III Melanoma: Results of a Multicenter Phase II Trial. *M. Safa, J. Lutzky, M. Chatterjee, J. Sussman, V. Bard, R. Baral, R. Das, A. Saha, R. Shukla, R. Reisfeld, L. Hutchins, A. Bhatnagar, K. A. Foon; University of Cincinnati, Cincinnati, OH; Mt. Sinai Cancer Center, Miami Beach, FL; Barrett Cancer Center, University of Cincinnati, Cincinnati, OH; The Scripps Research Inst., La Jolla, CA; University of Arkansas, Little Rock, AK; Titan Pharmaceuticals Inc., South San Francisco, CA*

TriGem is an anti-Id MAb that functionally mimics disialoganglioside GD2 which is highly expressed on melanoma cells. Sixty-nine patients with AJCC stage III melanoma were treated with TriGem. Of these, 25 also received high dose interferon (HDI) in addition to TriGem. Patients received the vaccine weekly for 4 weeks and then monthly until disease recurrence. Median age was 52 years (17- 86 years), 45 were males and 24 were females. There were 28 patients with N1 disease (1 node positive), 26 with N2 disease (2 to 3 positive nodes), 8 with N3 disease (4 or more positive nodes), and 7 with unknown number. The overall survival (OS) and relapse-free survival (RFS) for all patients were 82% and 62% respectively with a median follow-up of 24 months. OS for patients treated with TriGem alone was 72% (7 deaths among 44 patients) and for HDI plus TriGem was 96% (1 death among 25 patients). RFS for patients treated with TriGem alone was 50% and for HDI plus TriGem was 80%. In the E1694 Intergroup trial (personal communication, Dr. John Kirkwood) 440 patients were treated with HDI. OS and RFS were 78% and 62% (compared with 96% and 80% for HDI plus TriGem) respectively at a median follow-up of 24 months. We also studied the immune responses of HDI plus TriGem versus TriGem alone and found no significant differences, demonstrating that HDI does not suppress the immune response to TriGem. Toxicity of the vaccine was generally mild with a local reaction with swelling and pruritis lasting for 24 to 48 hours. In conclusion, our data suggests a clinical benefit of TriGem in stage III melanoma at a median follow-up of 2 years, particularly for patients treated with HDI plus TriGem. A randomized trial for stage III melanoma patients treated with HDI versus HDI plus TriGem is planned.